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09/426,111	10/22/1999	J. ROBERT MITCHELL	10991572-1	1439

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EXAMINER

BEX, PATRICIA K

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 11/29/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/426,111

Applicant(s)

MITCHELL, J. ROBERT

Examiner

P. Kathryn Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 September 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) 12-28 and 33-41 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-11, 29-32, 42-44 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 22 October 1999 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

4) Interview Summary (PTO-413) Paper No(s) _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-11, 29-32 and 42-44 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that "the modes of operation of claims 29 and 33 are not different (although claims 33 has features additional to this common mode of operation)". This is not found persuasive because it is these "additional features", i.e. adding a wash through the first port and exhausting the fluid through the second port, which make these modes of operation patentably distinct. Additionally, Applicant argues that restriction between Group I and II is not proper. Examiner points out that the claims of Group I does not require the specific configuration of the package of Group II, i.e. a second port on a side of the multiple fluid distribution channels opposite that of the first port. Therefore, these Groups are considered patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: #16a-c, in Figure 3. Correction is required.

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the array 12 in Figure 5 as described in the specification, see page 8, line 3. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Correction is required.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "38" has been used to designate both "cavity" and "manifold", see page 7, line 25 and page 9, line 27. Correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 5, 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5, line 2, the conditional term "can" is not a positive recitation, therefore, renders the claim indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-4, 29-30, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller *et al* (USP 5,273,905).

Muller *et al* teach a method and apparatus for performing polymer synthesis on a

substrate array 41 having multiple features. The package comprising a housing having a chamber 46 which is accessible through a first port 52. The chamber configured to receive the substrate. The housing including a first set of multiple fluid distribution channels 63, 64 disposed between the first port and the multiple features. Additionally, Muller *et al* teach adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port (column 22, lines 6-68, Figs.5-6).

9. Claims 1-5, 29-30, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Winkler *et al* (USP 5,384,261).

Winkler *et al* teach a method and package for performing polymer synthesis on a substrate array 401 having multiple features, i.e. linker molecules. The package comprising a housing having a chamber which is accessible through a first port 411. The chamber configured to receive the substrate. The housing including a first set of multiple fluid distribution channels 409 disposed between the first port and the multiple features. Additionally, Winkler *et al* teach adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port. Moreover, Winkler *et al* teach the use of valves 608 at the end of each channel such that if reagent is delivered to the top of the substrate it will flow through the open channel only (column 7, line 31- column 12, line 17, Fig. 4A-B, 5B, 6A).

10. Claims 1-5, 9, 29-30, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (WO 96/30124).

Freeman teaches a method and package for performing polymer synthesis on a

substrate array, e.g. slide or membrane (page 2, 3rd paragraph- page 3, 2nd paragraph) having multiple features. The package comprising a housing 82 having a chamber 86 which is accessible through a first port 88. The chamber configured to receive the substrate. The housing including a first set of multiple fluid distribution channels 89 disposed between the first port and the multiple features, i.e. linker molecules. Additionally, Freeman teaches adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port. Moreover, Freeman disclose wherein all of the channels are valved by a three-way valve mechanism 90 (page 16, last paragraph- page 17, 1st full paragraph, Figs.7A-B).

11. Claims 1-6, 9, 29-31, 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Juncosa *et al* (USP 6,225,109).

Juncosa *et al* teach a package for performing polymer synthesis on a substrate array 16, 140 having multiple features 50, 144. The package comprising a housing having a chamber 17, 130 which is accessible through a first port 23, 134. The chamber configured to receive the substrate (Figs. 2, 18). The housing including a first set of multiple fluid distribution channels 25, 142 disposed between the first port and the multiple features. Additionally, Juncosa *et al* teach adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port. Moreover, Juncosa disclose wherein all of the channels are micro or capillary sized, i.e. 10 microns to 5 millimeters. The substrate is then analyzed in a standard manner, i.e. fluorescence, eye, color, or laser reader. A CCD camera

or PC scanner can be used to record the results. (columns 4-10). Note: it is well-known within the art that channels 10 microns in diameter exhibit capillary action to retain fluid.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller *et al* (USP 5,273,905) or Winkler *et al* (USP 5,384,261), Freeman (WO 96/30124) or Juncosa *et al* (USP 6,225,109) in view of Besemer *et al* (USP 6,287,850).

Muller *et al* , Winkler *et al* , Freeman and Juncosa *et al* are silent regarding the use of a self-sealing closure member over the first port. However, the use of a self-sealing closure member is considered conventional in the art, see Besemer. Besemer *et al* teach a method and apparatus for directing fluid sample across a nucleic array for promoting hybridization between a target in the fluid sample and probes on the array. The device of Besemer uses an inlet port in

which a self-sealing septum is seated (Fig. 7). This insures that the seal is maintained even after the fluid is injected into the cavity since the pressure immediately forces the septum to reseal itself after the needle or other fluid injecting means is removed from the port. Thus an efficient and economical seal for retaining fluid in the cavity is provided.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Muller *et al* , Winkler *et al* , Freeman or Juncosa *et al* , the self-sealing septum, as taught by Besemer *et al* . Such a sealing means provides an efficient and economical seal for retaining fluid in the cavity (column 8, line 63- column 9, line 2).

15. Claims 7-8 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al* (USP 5,384,261) or Freeman (WO 96/30124) in view of Jun *et al* (Valveless Pumping using Tranversing Vapor Bubbles in Microchannels).

Winkler *et al* and Freeman as previously discussed above, do teach the use of valves to regulate the flow of fluid within the distribution channels. However, they do not disclose the specific use of a bubble formation device comprising a bubble nucleating resistor. Jun *et al* teach the formation of a stationary bubble formed by boiling, via a heater, a liquid flowing through a micro-channel to serve as an obstruction against flow in the channel and therefore function as a valve (Introduction and Theory sections, Fig. 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Winkler *et al* or Freeman the bubble forming device, as taught by Jun *et al* . Valves often leak with use and affect long term reliability. In addition, valve are often formed of delicate components that must be carefully

manufactured and installed for reliability. A bubble forming device requires no micro-mechanical moving parts, therefore reducing the need for valve components (abstract, introduction sections).

16. Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller *et al* (USP 5,273,905) or Winkler *et al* (USP 5,384,261), Freeman (WO 96/30124) or Juncosa *et al* (USP 6,225,109) in view of Katoot *et al* (USP 6,184,030).

Muller *et al* , Winkler *et al* , Freeman and Juncosa *et al* are silent regarding the step of communicating the result of the analysis to a location remote from the location of testing. However, communicating results obtained from analysis to a remote location is considered conventional in the art, see Katoot *et al* . Katoot *et al* teach a method using polymer films arranged in a matrix to provide the ability to perform multiple analyte determinations in a single sample. The data from the membranes may be displayed, printed, stored in a data storage means, input into a computer, sent to a remote data storage means or computer, or input into a trained neural network. Additionally, the system of Katoot *et al* may be configured to transmit the data to a remote location such as the office of a health care provider, health maintenance organization, etc (column 5 , line 56- column 6, line 3). This would aid the health care providers to evaluate data obtained from the patient samples and a form a diagnoses, prognoses, and develop a therapeutic strategy.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Muller *et al* , Winkler *et al* , Freeman or Juncosa *et al* , communication means, as taught by Katoot *et al* , in order to aid health care

providers to evaluate data obtained from the patient samples and a form a diagnoses, prognoses, and develop a therapeutic strategy (column 12, lines 10-24).

Conclusion

17. No claims allowed.
18. The prior art made of record and not relied upon which is considered pertinent to applicant's disclose are Goldberg *et al* , and Bruno *et al* . They are cited of interest in that they show different methods and apparatus for substrate preparations. Fields *et al* teach a bubble valve within a liquid delivery channel.
19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays from 6:00 am to 3:30 pm EST.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

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